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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,405	05/29/2002	Jean-Pierre Benoit	03715.0110	3630

22852 7590 01/04/2008  
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
LLP  
901 NEW YORK AVENUE, NW  
WASHINGTON, DC 20001-4413

EXAMINER
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TRAN, THAO T

ART UNIT	PAPER NUMBER
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1794

MAIL DATE	DELIVERY MODE
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01/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/069,405

Applicant(s)

BENOIT ET AL.

Examiner

Thao T. Tran

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-21 and 25-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-21 and 25-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/25/2007 has been entered.
2. Claims 1, 3-21, and 25-41 are currently pending in this application. No amendment has been made in the claims.
3. In view of the prior Office action, the prior art rejection of the claims is maintained as set forth below.

### ***Claim Rejections - 35 USC § 103***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claim 1, 3-21, and 25-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/13799.

WO '799 teaches a process for microencapsulating an active agent by coacervation, the process consisting of dissolving a polymer in an organic solvent, which contains the active substance; mixing the polymer/active agent solution (first phase) with another liquid (second phase) to form microdroplets of the active agent encapsulated in the polymer; quenching the mixture at 0-4°C with water or an aqueous solution (see Figures 1-3; page 9, 3<sup>rd</sup> paragraph; page

15, 2<sup>nd</sup> & 3<sup>rd</sup> paragraphs). WO '799 further discloses the organic solvent comprises ethyl acetate and an alcohol or a ketone of 1 to 3 carbon atoms, which include ethanol and propanol, meeting the requirement of the non-solvent in claims 1 and 41. The quenching solution contains water or an aqueous solution, meeting the requirement for the curing agent in claims 1 and 41. The second phase liquid and the quenching solution contain a surfactant, polyvinyl alcohol. (See page 22, last paragraph to page 23, 1<sup>st</sup> paragraph; page 26, 2<sup>nd</sup> paragraph; claims 1-49). The stirring is at a speed of 700 rpm and the particle size is 25 microns (see page 55, 1<sup>st</sup> paragraph; page 59, Example 15).

The reference teaches adding a mixture of ethyl acetate and an alcohol or ketone, instead of adding ethyl acetate first and then the alcohol or ketone. However, adding a mixture of ingredients has been held prima facie obvious over adding them sequentially since they would have given substantially the same results.

It is noted that since WO '799 uses the same organic solvent, non-solvent, and curing agent as presently claimed, the composition of the reference would inherently have the same properties and characteristics, such as dissolution or miscibility as the claimed invention. The solvents as indicated above in WO '799 are also non-chlorinated.

With respect to the concentration of the surfactant in the curing agent, WO '799 teaches a concentration of 01 to 10 wt% (see page 19, 1<sup>st</sup> paragraph), which appears to read on the instantly claimed ranges. WO '799 further teaches the polymer having a weight-average molecular mass of between 10,000 and 90,000 g/mol (see page 17, 1<sup>st</sup> paragraph).

WO '799 further teaches the polymer to be 75:25 PLGA (see page 16, ln. 24; page 35, ln. 7-8). Although the reference does not specifically teach the polydispersity index or the relative

dielectric permittivity, since the reference teaches the same polymer, the reference's polymer would inherently have the same properties as those of the presently claimed invention.

WO '799 further teaches that the solvent system is optimal at 0-4°C (see page 28, ln. 13).

Therefore, although the reference does not teach the coacervation temperature being equal to -4°C, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, that the coacervation temperature would have been adjusted to -4°C in order to bring forth maximal benefits attendant therewith. This is because Applicants have not disclosed the advantages of this temperature over other temperatures. And since WO '799 teaches that the coacervation temperature would be optimal at 0-4°C, the coacervation temperature taught by WO '799 would also include temperatures outside 0-4°C.

#### *Response to Arguments*

6. Applicant's arguments filed on 10/25/2007 have been fully considered but they are not persuasive.

Since Applicants' arguments are the same as before, the same response is presented and reiterated herein.

In response to Applicants' argument that the process as disclosed in the WO reference would not induce controlled desolvation of the polymer and allows deposition of the polymer at the surface of the active principle, it is noted that adding a mixture of ingredients has been held *prima facie* obvious over adding them sequentially since they would have given substantially the same results. Moreover, the use of one process over the other would have been determined through routine experimentation and dependent upon user's preference.

Applicants further argue that the WO reference differs from the presently claimed invention in that in the reference a single phase is obtained with the polymer dissolved therein, whereas in the presently claimed invention two immiscible phases are obtained with the polymer deposited on the active principle. This contention is incorrect. As pointed out previously and in paragraph 5 above, in the WO reference, microdroplets of the active agent encapsulated in the polymer are formed as the polymer/active agent solution (first phase) with another liquid (second phase) are mixed. Thus, the WO reference also teaches two immiscible phases as the end result where microdroplets of the active agent encapsulated in the polymer as presently claimed. Thus, the WO reference is obvious over the presently claimed invention.

In response to Applicants' argument that the chemicals in the reference are not used in the same way as presently claimed, it is noted that the prior Office action states that since the same chemicals are used in the reference, the composition of the reference would inherently have the same properties.

#### ***Contact Information***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thao T. Tran whose telephone number is 571-272-1080. The examiner can normally be reached on Monday-Friday, from 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton I. Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Thao T. Tran  
Primary Examiner  
Art Unit 1794

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